

PROJECT AGREEMENT

BETWEEN THE DEPARTMENT OF TRANSPORTATION OF THE
UNITED STATES OF AMERICA

AND

THE FEDERAL MINISTER OF TRANSPORT OF THE
FEDERAL REPUBLIC OF GERMANY

CONCERNING RESEARCH COOPERATION
IN TRAFFIC SAFETY

1. **AUTHORITY**

This Project Agreement (hereinafter referred to as "this Agreement") is entered pursuant to the Memorandum of Understanding regarding Cooperation in the Field of Transportation between the Department of Transportation of the United States of America and the Federal Minister of Transport of the Federal Republic of Germany (hereinafter referred to as "the Parties") signed at Washington, D.C., September 3, 1975.

2. **PURPOSE**

The overall purpose of this Agreement is to establish a program of research cooperation in traffic safety to measure the influence of selected drugs on driving performance using a driving simulator.

The cooperation is directed toward exchanging information on most effective technology so as to avoid unnecessary duplication of effort and minimize cost to both Parties. In carrying out the terms of this Agreement, project management responsibility for the Department of Transportation will be assigned to the National Highway Traffic Safety Administration (NHTSA) and project management responsibility for the Federal Minister of Transport will be assigned to the Road Research Institute (Bundesanstalt für Strassenwesen (BAST)).

"Cooperation under this Agreement is subject to the applicable laws and regulations of the Parties."

3. PROJECT OFFICERS

- a. Designation. Within thirty days of the entry into force of this Agreement, the Parties will each designate a Project Officer to conduct cooperative activities described in the Annex.
- b. Responsibilities. Project Officers will be responsible for the accomplishment of the tasks and objectives set out in this Agreement and in the Annex, and will be the principal points of contact between the Parties for detailed arrangements and exchanges related to this Agreement. Direct contact on technical matters may be made through the contractors (see paragraph 4).

4. CONTRACTORS

In the event that either Party employs a contractor to conduct or participate, on its behalf, in any exchanges pursuant to this Agreement, the name of the contractor and the scope of its assignment and authority shall be notified to the other party.

5. SCOPE OF WORK

The scope of work to be accomplished by the Parties, individually and jointly, is set out in detail in the Annex to this Agreement.

6. FUNDING

- a. The participation of each Party in the project is subject to the availability of appropriated funds.
- b. NHTSA will bear the direct costs (e.g., salary, travel, subsistence) associated with the participation of its personnel in the project, as well as the costs of any language services it may require.
- c. NHTSA agrees to transfer to the BAST the sum of US \$392,644 (three hundred ninety two thousand, six hundred forty four) based on the July 18, 1988, exchange rate of DM 1.87 = US \$1.00, in payment for its share of the execution of this research project using the DAIMLER-BENZ driver simulator. These funds will cover all expenditures supported by BAST including the cost of travel and subsistence incurred by

BAST for meetings required by NHTSA. No other transfer of funds between the Parties is envisaged in connection with the project.

- d. BAST will provide NHTSA with a complete and detailed accounting report on all funds expended for this project.

7. DATA ANALYSIS AND REPORTS

BAST will be responsible for analyzing the data from each driving scenario using appropriate statistical methodology and for preparing draft and final reports for each study completed under this Agreement. BAST will provide NHTSA at least five copies of each final report.

8. DISCLAIMER

Each Party will exercise its best efforts to ensure the accuracy of all data transmitted to the other Party pursuant to this Agreement, but the accuracy of such data is not guaranteed. Each Party will use the other's data at its own risk and may not hold the other Party responsible in the event of claims arising from the use of such data.

9. LAND BERLIN

This Agreement shall also apply to Land Berlin, provided that the Government of the Federal Republic of Germany does not make a contrary declaration to the Government of the United States of


America within three months of the date of entry into force of this Agreement.

10. DURATION

- a. This Agreement shall enter into force on the date of signature and shall remain in force for a period of two years. It may be renewed by mutual agreement of the Parties in writing.
- b. This Agreement may be terminated by either Party on sixty days' written notice.

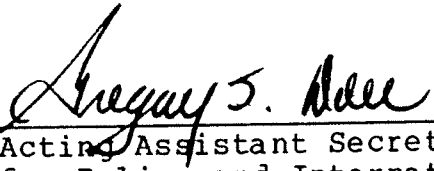
DONE at Washington, D.C., on September 14, 1988, in duplicate, in the English and German languages, both texts being equally authentic.

FOR THE FEDERAL MINISTER OF
TRANSPORT OF THE FEDERAL
REPUBLIC OF GERMANY:



Director General
for Transportation Policy
Heinz Sandhager

FOR THE DEPARTMENT OF TRANSPORTATION
OF THE UNITED STATES OF AMERICA:



Acting Assistant Secretary
for Policy and International
Affairs
Gregory S. Dole

ANNEX

DESCRIPTION OF RESEARCH AND SCOPE OF WORK

1.0 Introduction

Previous crash investigation research suggests the potential for a sizable drugs and driving problem. However, we cannot say at this time which, if any, drugs present a hazard to the safe operation of a motor vehicle. A number of studies have revealed the presence of drugs in from 10% to 25% of fatal and seriously injured drivers. However, the mere presence of drugs in drivers, at any incidence rate, does not necessarily mean that the use of the drug was causally related to the crash. Only if the drug occurs significantly more frequently in crash-involved drivers than it does in non-crash-involved drivers can it be considered a possible causal factor. The greater the overrepresentation of a drug in the crash-involved sample, the more likely the drug is a significant highway safety hazard. Unfortunately, we do not have drug frequency rates for non-crash drivers, and the possibility of obtaining this information, which would require collecting volunteered blood samples from drivers stopped at checkpoints, is relatively remote.

An alternative approach that can be used to determine whether drugs precipitate crashes is to examine their effects on driver performance in a driving simulator. Sufficient driver impairment in this situation would lend support to the position that the drug is a real world crash hazard. It is critical that the simulator used in this type of research be as realistic as possible, so that the results can be more easily generalized to real world driving situations. Based on a review of available driving simulators worldwide, we believe that the simulator developed by Daimler-Benz (Mercedes) in Berlin is the most "realistic" and sophisticated driving simulator currently in existence. Its key elements are a highly realistic motion system with six degrees of freedom, and a projection system that simulates the vehicle environment with a sharply focused seamless 180 degree picture in the driver's visual field. A complex mathematical model of dynamic vehicle behavior simultaneously guides a number of computers in simulating motion, reaction forces of the steering wheel, brake and accelerator pedals, as well as the visual field and noises associated with a simulated drive. Using this simulator, we would be able to program a variety of routine and emergency driving situations, varying the road type and condition, weather conditions, and visibility. Driver performance (e.g. type and severity of accidents, and dangerous situations avoided) could be recorded for various drug and dosage conditions.

The purpose of this project is to assess the degree of driver impairment associated with specific drugs and dose levels, as measured using the Daimler-Benz (Mercedes) driving simulator in Berlin. This cooperative agreement is between the U.S. Department of Transportation (DOT) and the Ministry of Transport of the Federal Republic of Germany. The National Highway Traffic Safety Administration (NHTSA) is the unit of the U. S. DOT responsible for the U. S. role in the project. The Bundesanstalt fur Strassenwesen (BAST) is the German transportation research institute that will manage the German role in the project. The actual research data will be collected in Berlin where the Daimler-Benz (Mercedes) driving simulator is located. All interaction with Daimler-Benz personnel will be coordinated by BAST. NHTSA will deal directly with BAST for this project, and BAST will oversee other parties involved in the execution of the research. The implementation of the research, including the medical supervision of participating subjects and the laboratory blood tests required, will be supervised by personnel from the Institute for Legal Medicine (Institut fur Rechtsmedizin) in Berlin. Daimler-Benz will have responsibility for the preparation of the simulator driving scenarios that will be experienced by the participating subjects, and the actual running of the simulator.

The following sections provide details regarding what specific drugs are to be studied, how subjects will be recruited and supervised, what experimental procedures will be used, what driving tasks will be run on the simulator, and what driving performance and other self-report measures will be recorded. A summary of the proposed schedule, the specification of who will have responsibility for what activities, and the estimated costs are also provided.

2.0 Selection of drugs and dose levels.

Two drugs will be evaluated, each at two dose levels and a no drug condition. These drugs were selected because of their potential as highway safety hazards. Valium (representing the class of tranquillizers) appears frequently among drugs found in fatally injured drivers. Valium is also widely used in the general population. The antihistamine selected, diphenhydramine, represents a class of widely used over-the-counter drugs that has been shown in the laboratory to have the ability to impair driving related performance. The two dose levels specified for each drug represent typical dosages.

Tranquilizer - Diazepam:

No drug, 0.11 mg./kg, and 0.22 mg/kg.

These dose levels translate to approximately 7.5 mg. and 15 mg. doses for a 70 kilogram person.

Antihistamine - Diphenhydramine:

No drug, 0.71 mg./kg, and 1.07 mg/kg.

These dose levels translate to approximately 50 mg. and 75 mg. for a 70 kilogram person.

The doses administered shall be expressed in terms of mg/kg bodyweight, to minimize variability between subjects.

We are most interested in studying the effects of the drugs on drivers that are occasional users, i.e. individuals that take the drug as needed on a prescription basis or individuals that use the drug occasionally on a recreational basis. Therefore, single acute doses shall be studied.

3.0 Procedures.

3.1 Subjects.

The Institute for Legal Medicine (Insitut fur Rechtsmedizin) in Berlin will be responsible for implementing the recruitment, selection, and supervision of subjects who participate in this research.

3.1.1 Subject Selection.

Between 60 and 120 volunteers will be solicited from the Free University of Berlin (10 to 20 subjects for each condition - no drug and two dose levels). Only male licensed drivers between the ages of 21-25, weighing between 65-75 kilograms will be selected. Prospective volunteers will be screened to obtain both medical and drug histories. Only persons who show no medical contraindications, who are only occasional users of the drugs being studied, and who agree to be drug free prior to participation in the study, will be considered. Driving experience is another factor that will influence subject selection. Only individuals that drive between 3,000 KM and 10,000 KM per year will be considered for selection. In addition, the subjects should not be experienced driving with power steering.

3.1.2 Medical supervision during the course of the study.

The Institute for Legal Medicine will have the primary role in the medical and drug history screening of volunteers. Medical personnel (doctor or nurse) will be present during the course of each experimental session. At the conclusion of each experimental session, the subjects will remain under medical supervision for a specific period of time, after which they will be driven home.

3.2 Experimental Design

The drugs shall be studied independently. All of the simulator data for the first drug shall be collected before the simulator runs for the second drug are initiated. Accordingly, this project actually involves two phases, each using the same subject recruitment and processing procedures as well as the same simulator scenarios and driving performance measures. The evaluation of each drug may be considered a stand-alone study and a separate report shall be prepared describing its results.

The experimental design is essentially the same for each study. In each case, a between-subject design shall be used with a target sample size of between 10 and 20 subjects per condition for each of the three conditions (no drug, low and high dose conditions). Note that a pilot test, with from 5 to 9 subjects may be run prior to initiation of the first drug study. This will enable all logistic and organizational problems (subject transport and supervision, simulator set up and run, data collection and reduction, etc.) to be tested and resolved.

3.3 Experimental Procedures

This section sketches what will happen to a volunteer subject from the time of his arrival at the laboratory/simulator until the time he is safely home.

After reporting to the study site, the subject will be asked to first give a urine specimen. The purpose of collecting the urine specimen is to screen for alcohol and other licit or illicit drugs in the subject's system, to verify that the subject is starting the session drug free. After the urine specimen has been collected, the subject will take the prescribed drug (or nothing). When the drug has had sufficient time to be absorbed into the bloodstream, the simulator drive will commence. Immediately following the simulator drive, a blood sample will be drawn to obtain a measure of the drug-blood concentration. The simulator drive itself (described below) will run about 20 minutes. Following the collection of the blood sample, a short questionnaire (also described below) will be administered, and the subject will be asked to complete a series of laboratory psychomotor tasks independent of the simulator. Following this, the subject will be monitored by the medical personnel present until it is determined that the acute drug effects are over and it is safe for the subject to be driven home.

3.4 Simulator Scenarios.

Prior to drug dosing each subject will be exposed to a ten minute training session on the simulator. This will ensure that each subject is sufficiently familiar with how the simulator operates. On the day of the experimental session the subject will receive one drug condition (no drug, low or high dose) and then be exposed to a 20 minute simulator drive. At the beginning of the simulator test drive, the subject will be exposed to a straight 2-lane road, and instructed to maintain a cruising speed of about 80 km/hr unless the situations he encounters require a different speed (e.g., car following, stopping at an intersection, etc.).

During the course of his 20 minute drive, the subject will encounter a number of different scenarios that will impose varying demands on him. Between each scenario, the driver will drive along a straight road for about 30 seconds. This will allow him time to get his speed back up to 80km/hr. Set up procedures for the training and test drives will require an additional 10 minutes of simulator time. The general description of each scenario is presented below:

Traffic Light Change from Green to Red.

Qualitative Description of Scenario. In this situation, the subject will approach a traffic light controlling the flow of traffic. This drive will be under dry road conditions in clear weather. Under these conditions, the driver will be exposed to two different situations, one requiring a QUICK RESPONSE, and the other requiring a NORMAL RESPONSE. In the QUICK RESPONSE situation, the driver will be cruising at about 80 km/hr. and will see the traffic signal change from green to yellow to red at 75 meters from the intersection. In the NORMAL RESPONSE condition, the traffic signal will change when the driver is 110 meters from the intersection.

Response Measures.

Driver attempts to stop

- o Reaction time to initiation of braking
- o Vehicle velocity when light changes
- o Maximum deceleration
- o Position when stopped (in relation to intersection - \pm number of meters from the edge of the intersection)

Driver travels through the red light

- o Does driver accelerate (yes, no)
- o Reaction time to initiation of acceleration
- o Maximum acceleration
- o Color of signal (yellow or red) when the driver enters the intersection

Following Situation.

Qualitative Description of Scenario. In this situation, a driver will be cruising at approximately 80 km/hr following traffic in front of him. This drive will be under dry road conditions in clear weather. The driver will be instructed to maintain a safe and comfortable following distance for some period of time (e.g., 30 seconds). To add realism to the situation, there may be occasional oncoming traffic going in the opposite direction, though that information would not be relevant to the task at hand in this situation. While in a steady state condition, there

will be two situations to which the driver will be exposed, one requiring a QUICK RESPONSE, and the other requiring a NORMAL RESPONSE. In the QUICK RESPONSE condition, the lead car will decelerate as rapidly as possible and come to a complete stop, and we will assess the response of the following vehicle. In the NORMAL RESPONSE condition, the lead car will break, but its deceleration will be gradual, not requiring an extraordinary response for our driver-subject to compensate for the slowdown. In this situation, the lead vehicle will decelerate to about 40km/hr and maintain this velocity for some period of time (e.g., 30 seconds).

Response Measures.

- o Time gap between the vehicles that the driver accepts prior to the lead vehicle initiating deceleration (also, some measure as to the variability of this time gap - does the driver maintain a relatively constant time gap or does it vary considerably?). The mean time gap and its standard deviation (prior to initiation of deceleration) may be appropriate measures.
- o Following lead vehicle deceleration (Quick Response Condition)
 - Reaction time to initiation of braking
 - Maximum deceleration
 - Simulated vehicles final position (stopped in road behind lead vehicle - number of meters separation, collision with lead vehicle, off the road to avoid a collision
 - closest distance to lead vehicle (number of meters) during deceleration
- o Following lead vehicle deceleration (Normal Response Condition)
 - Reaction time to initiation of braking
 - Maximum deceleration
 - Closest distance to lead vehicle (number of meters) during deceleration
 - Final time gap that driver maintains (mean, standard deviation) following deceleration of lead vehicle.

Dart-Out Situation.

Qualitative Description of Scenario. In the dart-out situation, the driver will again be cruising at approximately 80 km/hr on a dry roadway in clear weather. In one condition (NORMAL RESPONSE), there will be a bus parked along the curb, obstructing the driver's view of anyone behind the bus. A pedestrian will cross the street into the path of our subject driver, starting from a position which is hidden by the bus. This will occur when the subject driver is far enough from the bus so that he has to react to avoid hitting the pedestrian, but not in an emergency manner. In a second case, requiring a QUICK RESPONSE, a car will enter the right lane suddenly from the side of the road. In this situation, the driver will have to react very quickly to avoid a collision.

Response Measures.

- o Reaction time to initiation of deceleration
- o Maximum deceleration
- o Type of avoidance maneuver (none, swerved off road to the right, swerved into the opposing traffic lane, decelerated to a stop)
- o Collision with object (yes or no)

Snow on the Road Situation.

Qualitative Description of Scenario. As in previous situations, the driver will be cruising at about 80 km/hr. Road conditions will initially be dry. In this situation, the driver will eventually encounter a section of roadway that is covered with snow. This section of roadway will be colored white with some snow banks along the side of the road. The coefficient of friction on the snow covered portion will be reduced so that vehicle control is more difficult. However, the friction coefficient should not be so low as to simulate a sheet of ice.

Response Measures.

- o Type of driver compensation for snow (none, accelerate, let up on accelerator pedal, apply brake, maximum amount of acceleration or deceleration)
- o Result of driver compensation for snow (stays in his traffic lane, slides off the road on right but maintains control, slide off road on right but loses control - accident, slides into opposing traffic lane but maintains control, slides into opposing traffic lane but loses control - accident).

Merge Into Traffic Situation

Qualitative Description of Scenario. In this situation the driver is stopped at an intersection controlled by a 2-way stop sign. He is instructed to make a right turn and merge into crossing traffic. Two vehicles will be travelling down the crossroad that the driver must turn on to. The time gap between the first vehicle on the crossroad and the driver will be relatively short (e.g., 5 seconds) so that the driver would have to accelerate somewhat rapidly to safely make the turn and merge in front of the first crossing vehicle. The time gap between the first and second vehicle on the crossroad will be somewhat larger (e.g., 8 seconds) so that the driver does not have to accelerate as rapidly to successfully execute the turn and merge in between the crossing vehicles. The driver may also allow both crossing vehicles to pass before merging into crossing traffic.

Response Measures

- o Location of driver turn and merge - before first crossing vehicle, in between first and second crossing vehicle, after second crossing vehicle
- o Time gap between driver and approaching crossroads vehicle when the turn is initiated
- o Maximum acceleration during the turn and merge maneuver
- o Collision with crossroads vehicle (yes or no)

Narrow Road Situation

Qualitative Description of Scenario. The driver will encounter a section of roadway where pylons are used to make the road much more narrow than normal. The driver will attempt to travel through these pylons without knocking any over.

Response Measures

- o Maximum change in vehicle velocity during pylon course
- o Number of pylons knocked over

Straight Road Situation

Qualitative Description of Scenario. At the end of the test ride the driver will drive along a straight section of road for some period of time. The objective here will be to look at the driver's ability to maintain lane position as an indication of the degree of fatigue he is experiencing.

Response Measures

- o Number of departures from traffic lane (off the road or into the opposing traffic lane)
- o Increase in weaving within driver's own traffic lane (yes or no)
- o Difference in average speed maintained in this situation from 80 km goal (plus or minus)

4.0 Post Simulator Drive Test Procedures.

At the completion of the simulated drive, each subject will be asked to fill out a questionnaire. The questionnaire will include items asking how much driving experience the driver has had, and how long he has been licensed. A mood section will also be included along with items tapping basic demographic and personality information. Following completion of

the questionnaire, each subject will be required to perform a number of laboratory psychomotor tasks, such as tracking, divided attention and reaction time tasks. It is hypothesized that the drugs taken will also influence performance in these cases, thereby serving as another measure of the drug effects on behavior. The effects of different drugs on performance on these separate activities will be compared to performance measures on the simulator.

5.0 Data Analyses.

Regarding outcome data on the driving simulator, the relationship between driver performance and drug dose levels will be assessed for each scenario encountered. At a minimum, the response measures listed above for each driving scenario will be analyzed using appropriate statistical methodology to determine the nature and extent of performance changes associated with each drug and dose level. BAST will be responsible for the data analyses.

6.0 Organizations and key personnel

As indicated above, three German organizations will be involved in the implementation of this study, along with NHTSA representing the United States. Each organization and the key personnel involved in this project from that organization are described below:

Bundesanstalt fur Strassenwesen (BAST) is the German federal government's research institute that sponsors and conducts highway safety research. A portion of that work deals with the effects of alcohol and drugs on driving. BAST will be the German government agency responsible for setting up and carrying out this research project. They will subcontract with the other two German organizations listed below, as appropriate. The key personnel from BAST working on this project are:

Dr. med. Bernd Friedel, Head, Research Department
 Dr. med. Sabine Joo, Head, Medical Unit, Research Department
 Dipl. - Psych. Ute Grubel-Mathyl, Scientist, Medical Unit

BAST will be represented by Dr. med. Friedel or his designee in all of its interactions with NHTSA. The mailing address for BAST is:

Bundesanstalt fur Strassenwesen (BAST)
 Postfach 100150
 Breuderstrasse 53
 D-5060 Bergisch-Gladbach 1
 Federal Republic of Germany

The Institute for Legal Medicine is an agency of the Free University of Berlin. The Institute is an organization that conducts forensic research. It has personnel and facilities to undertake medico-legal research, including morphological, biomechanical, chemico-toxicological, and serological studies. Research in traffic medicine falls within its expertise, including studies of the effects of alcohol and drugs on driving behavior. Personnel and facilities are in place to conduct the needed medical supervision and laboratory work this project requires. The key personnel that will work on this project from the Institute are:

Dr. Klaus-Steffen Saternus, Deputy Director of the Institute
 Prof. Dr. Ernst Klug, Head, Chemical-Toxicology Department
 Dr. Kurt Wagner, Scientist
 Mr. Peter Klostermann, Sociologist

The mailing address for the Institute for Legal Medicine is:

Institute fuer Rechtsmedizin der FU Berlin
 Hittorfstrasse 18
 D-1000 Berlin 33
 Federal Republic of Germany

Daimler-Benz, AG is a major German auto manufacturer with research facilities in Berlin. Daimler has built a state-of-the-art driving simulator in Berlin. The data for this project will be collected from subjects driving on this driving simulator. The key Daimler personnel that will be associated with this project are:

Dipl. -Ing. Wilfried Kading, Department Manager, Driving Simulator
 Research Group, Daimler-Benz AG, Berlin

Dr. Bernd Strackerjan, Department Manager, Research Group
 Daimler-Benz, Stuttgart

Mr. Stefan Hahn

The mailing address is:

Daimler Benz AG
 Forschungsgruppe Berlin/ Fahrsimulator
 Daimlerstrasse 23
 D-1000 Berlin 33
 Federal Republic of Germany

The NHTSA shall be represented by Theodore E. Anderson, Research Psychologist, Office of Driver and Pedestrian Research, Research and Development. His correct mailing address is:

Theodore E. Anderson, Research Psychologist
Office of Driver & Pedestrian Research (NRD-42)
National Highway Traffic Safety Administration
400 Seventh St., SW (Room 6240)
Washington, DC 20590, USA

7.0 Cost Considerations.

The following items summarize how funds for this project are being allocated, and from where the support comes. These estimated costs are all reported in Deutsche Marks (DM). A summary statement of the estimated U. S. cost in dollars at \$392,644, based on a July 18, 1988 exchange rate of DM 1.87 = \$ 1.00, is also included.

Organization/ Item	German Contributions (DM)	NHTSA Contribution (DM)	Total (DM)
<u>I. Daimler-Benz</u>			
1. Personnel Costs	7,606	17,748	25,354
2. Simulator Costs			
2.1 Preparation (10 hours)	15,390	35,910	51,300
2.2 Test runs (100 hours)	153,900	359,100	513,000
(sub-totals)	DM 176,896	412,758	589,654
3. Estimated German Industrial Tax (10%)	17,690	41,276	58,966
SUB-TOTALS	DM 194,586	454,034	648,620
<u>II. Institute for Legal Medicine, Berlin</u>			
1. Personnel Costs	86,890	26,000	112,890
2. Cost for test subjects	---	96,600	96,600

7. Cost Considerations (continued)

Organization/ Item	German Contributions (DM)	NHTSA Contribution (DM)	Total (DM)
<u>II. Institute for Legal Medicine, Berlin (continued)</u>			
3. Cost for lab tests			
3.1 Screening for drugs & alcohol	—	38,280	38,280
3.2 Lab test for liver enzymes, creatinine and others	—	4,260	4,260
4. Costs for material	—	6,270	6,270
5. Overhead	1,600	6,400	8,000
SUB-TOTALS:	DM 88,490	177,810	266,300
<u>III. Bundesanstalt für Strassenwesen (BAST)</u>			
1. Personnel Costs	104,000	67,100	171,100
2. Travel Costs	2,250	21,500	23,750
3. Equipment Maintenance (other than simulator)	3,000	—	3,000
4. Computer time	20,500	—	20,500
5. Report preparation (including translations, graphics, etc.)	—	10,800	10,800
6. Overhead	10,000	3,000	13,000
SUB-TOTALS:	139,750	102,400	242,150

SUMMARY OF U.S. AND GERMAN CONTRIBUTIONS

<u>Contributions</u>	<u>Total</u>		
	<u>German</u>	<u>U. S. A.</u>	<u>Total Cost</u>
TOTALS (DMs)	DM 422,826	DM 734,244	DM 1,157,070
Estimated Totals	US\$ 226,110	US\$ 392,644	US\$ 618,754

(based on exchange rate of DM 1.87 = U.S.\$ 1.00 as of July 18, 1988)

Percentage contributions	36.5%	63.5%	100%
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The U. S. contribution to this project will be made when this agreement is signed and the necessary funds are available to NHISA. The U. S. costs will be split-funded in two parts, US\$ 177,000 in Fiscal Year 1988 and US\$ 215,644 in Fiscal Year 1989 (beginning on October 1, 1988). Estimates for this work were originally prepared in DM. These U. S. dollar amounts are based on the July 18, 1988 exchange rate of DM 1.87 = \$1.00. If the exchange rate changes from the time this document has been prepared and the time funds are transferred, the DM estimates shall be the basis on which the U. S. dollar obligation shall be calculated. Payments shall be transmitted to BAST on Account # 11900505 of the Bundeskasse Bonn at Postgiroamt Koeln (BLZ 37010050), Ref. # 1221/1211-11902.

The funds supplied by the U. S. government shall be understood to cover all expenditures supported by BAST in the performance of this project, including the cost of travel and subsistence allowance incurred by BAST for meetings required by NHISA.

8.0 Milestones for Schedule of Each Study.

For each drug studied, the estimated time to complete the steps listed below are indicated:

<u>Milestone</u>	<u>Time from start of study</u>
Complete subject recruitment	2 months
Initiate simulator runs for dosed subjects	4 months
Complete simulator testing	6 months
Complete performance data reduction	7 months
Complete performance data analyses	9 months
Submit draft final report	10 months
Submit final report	12 months

9.0 Final Reports.

BAST shall assume the primary responsibility for preparing final reports for each study completed under this agreement. At a minimum, there will be two reports, corresponding to the two drugs being studied. Both English and German language versions of each report shall be prepared. As a minimum, the reports should contain an overview of the research approach, specification of the methodology, the research findings, analyses and interpretation of those findings and analyses, conclusions and recommendations for future research. NHISA shall be able to review drafts of final reports from this project before they are released to the public. The draft final report shall be accompanied by an accounting of the total funds expended to complete the project. One camera-ready version suitable for off-set printing, and five (5) duplicated copies of each final report shall be submitted within 90 days following completion of the project.

Each report prepared shall also be accompanied by an EXECUTIVE SUMMARY, a 2-3 page summary of the project that could stand alone as an overview of the project results and conclusions.